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10/540,934

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John W Harmon

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BANNER & WITCOFF

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WASHINGTON, DC 20001

EXAMINER

WHITEMAN, BRIAN A

ART UNIT

PAPER NUMBER

1635

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/31/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/540,934

Applicant(s)

HARMON, JOHN W

Examiner

Brian Whiteman

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 8-13, 16 and 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14, 15, 17-24, 41-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
- Paper No(s)/Mail Date 11/9/06.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

Claims 1-44 are pending.

Applicant's traversal, the amendment to claims 1, 22, and 24 and the addition of claims 41-44 in paper filed on 11/9/06 is acknowledged and considered by the examiner.

### *Election/Restrictions*

Claims 25-40 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and Claims 8-13 and 16 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6/6/06.

### *Priority*

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

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U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32

USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/437,392 and 60/471,829, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application.

Instant claim 3 does not have written support '1 to 100 pulses' in either '392 or '829. Thus, instant claim 3 only has priority to the PCT filed on 12/29/03.

Instant claim 5 does not have written support '10 to 5,000 V/cm' in either '392 or '829. Thus, instant claim 5 only has priority to the PCT filed on 12/29/03.

Instant claim 14 is does not have written support in application '392 for 'HIF-1alpha'. Thus, instant claim 14 only has priority to '829 filed on 5/20/03.

Instant claim 18 does not have written support 'one or more nucleic acids encoding at least two growth factors' in either '392 or '829. Thus, instant claim 18 only has priority to the PCT filed on 12/29/03.

Instant claim 22 and claims dependent therefrom does not have written support for the limitation 'applying between 1 and 20 pulses of between 500 and 2,000 V/cm and between 10 to 1000 microseconds' in either '392 or '829. Thus, instant claim 22 and claims dependent therefrom only has priority to the PCT filed on 12/29/03.

***Information Disclosure Statement***

Contrary to applicant's assertion that the examiner has not considered the US patent cited on the IDS filed on 11/9/06. The US patents was cited with the election/restriction mailed on 5/10/06.

***Specification***

The abstract of the disclosure does not commence on a separate sheet in accordance with 37 CFR 1.52(b)(4). A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

Applicant did not address the objection to the specification.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3-5 and 22-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

New matter rejection:

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The limitation 'electric field intradermally' claims 3-5 and the limitation 'applying between 1 and 20 pulses of between 500 and 2,000 V/cm and between 10 and 1000 microseconds intradermally to the wounded tissue at the wound site, whereby wound healing is stimulated' in claim 22 and claims dependent therefrom, the limitations in claims 3-5 and 22 and claims dependent therefrom is not supported by the instant specification. There appears to be no written description of the limitation in the application as filed. See MPEP § 2163.06. Applicant cites paragraph 52 for support for the limitation.

Paragraph 0052 recites:

Animals were electroporated at the site of injection within two minutes of plasmid administration, using a square wave electroporator (ECM 830, BTX Genetronics, San Diego, CA). A custom designed pin electrode, consisting of two 10 mm rows of parallel needles separated by 5 mm was used to apply the electroporation voltage (Figure 8). Between 6 to 18 square wave pulses were administered, at an amplitude of between 400 and 1800 volts, a duration of between 100 ~ to 20 ms, and an interval between pulses of 125 ms (Figure 9).

The limitations in the amended claims are not disclosed in the paragraph cited by the applicant. The paragraph does not specifically disclose the ranges set forth in claims 3-5 and 22-24 and applying an electric field intradermally. The ranges used in the example are narrower than the ranges recited in the claims. Therefore, there is nothing in the specification that supports the new limitations as set forth in the instant claims.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to

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modifications that the inventor might have envisioned, but failed to disclose." *Lockwood v.*

*American Airlines Inc.*, 41 USPQ2d 1961, 1966 (CAFC 1997).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "wounded tissue is at the wound's border" in claim 42 is a relative term which renders the claim indefinite. The term "wounded tissue is at the wound's border" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The metes and bounds of the term are undefined because it is not apparent how a wounded tissue can only be at the wound's border. It is not apparent what the applicant is trying to claim.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 3, 5, 6, 7, 19, 21, 41, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang et al. (US 6,972,013) taken with Glasspool-Malone et al. (Mol. Therapy 2000, 2:140-6). Zhang teaches intradermal delivery of naked DNA followed by electroporation (column 4, Figure 11). Zhang teaches that efficient expression of the DNA requires a regulatory sequence (column 8). Zhang teaches that, "some electroporation applications, the electric field comprises a single wave pulse on the order of 100 to 500 V/cm, of about 10 to 60 ms, duration" (column 3). "Such a pulse may be generated, for example, in known applications of the Electro Square Porator T820 or ECM830, made by the BTX Division of Genetronics, Inc." See column 3. In the instant specification, the Applicant uses ECM830 for square wave pulse. Zhang teaches, "Although various terms are frequently used herein in the singular, the singular forms of the terms include multiple pulses". See column 7. Zhang teaches that a nucleic acid encoding a growth factor can be used in the method (column 11). A plasmid can be used in the method (column 12). Zhang teaches using a square wave pulse wherein the pulse is at least 50 V for about 10 up to 20 ms (column 15 and 21). The pulse length can be adjusted from 5  $\mu$ sec to 99 ms (column 21). DNA expression in the epidermis can be used in the acceleration of wound

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healing (column 45). However, Zhang does not specifically teach intradermally applying the electric field.

However, at the time the invention was made, interdermally applying was used to improve the delivery of DNA to cells in a subject as exemplified by Glasspool-Malone et al. (page 140). In addition, Glasspool-Malone teaches using pin electrode (page 141).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely to apply the electric field intradermally. One of ordinary skill in the art would have been motivated to combine the teaching to improve the delivery of the DNA to the cells in vivo.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to the combine the teaching of Zhang taken with Glasspool-Malone, namely to administer to a wound site in a patient a nucleic acid encoding growth factor operably linked to a promoter to the skin via electroporation. One of ordinary skill in the art would have been motivated to practice the claimed method because electroporation to the skin is non-invasive route of gene delivery and the electrodes are user-friendly electrodes. In addition, one of ordinary skill in the art would have been motivated to administer a nucleic acid encoding a growth factor to a wound site because growth factors are known to one of ordinary skill in the art for treating wounds.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely to use pin electrodes. One of ordinary skill in the art would have been motivated to practice the

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claimed method because pin electrodes are suitable electrodes for delivering an electric field to a subject. See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely to apply the electric field in pulses. One of ordinary skill in the art would have been motivated to practice the claimed method because Zhang teaches that number of pulses appeared to have little influence on the level of stimulation of gene expression (column 45). See *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely to use an electric field from 10 to 5,000 V/cm. One of ordinary skill in the art would have been motivated to practice the claimed method because electric field for in vivo electroporation are preferably from about 700 V/cm to 1300 V/cm as exemplified by Zhang (column 21). See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely to use a square wave pulse. One of ordinary skill in the art would have been motivated to practice the claimed method because the square wave pulse is a preferred pulse for delivering a nucleic acid in vivo as exemplified by Zhang (columns 15 and 21). See *Sinclair & Carroll Co. v. Interchemical Corp.*

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely

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to administer to a wound site in a patient a plasmid comprising a nucleic acid encoding growth factor operably linked to a promoter to the skin via electroporation. One of ordinary skill in the art would have been motivated to practice the claimed method because plasmids are suitable vector for use in electroporation of DNA to skin cells as exemplified by Zhang (Column 39).

See *Sinclair & Carroll Co. v. Interchemical Corp.*

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone, namely to surgically removed the wound eschar before administering to a wound site in a patient a plasmid comprising a nucleic acid encoding growth factor operably linked to a promoter to the skin via electroporation. One of ordinary skill in the art would have been motivated to practice the claimed method because to avoid delivering the nucleic acid to the dead skin tissue.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Applicant's arguments, see pages 10-12, filed 11/9/06, with respect to 103 rejection have been fully considered and are persuasive. The rejection of claims 1-7, 14, 15, and 17-24 has been withdrawn because of the amendment (electric field intradermally) in claim 1 and (applying between 1 and 20 pulses of between 500 to 2000 V/cm and between 10 to 1000 microseconds intradermally) 22. However, upon further consideration, a new ground(s) of rejection is made in view of the amendment to the claims.

Claims 1, 4, 15, and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhang taken with Glasspool-Malone as applied to claims 1, 2, 3, 5, 6, 7, 19, 21, 41, and 44

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above, and further in view of Bureau et al. (WO 99/01157, English equivalent is US 6,528,315) taken with Ruben et al. (US 20030186904). Since the WO document is in French, the teaching of US 6,528,315 will be cited in the rejection.

Zhang taken with Glasspool-Malone do not specifically teach the pulse is from 1 microsecond to 5 seconds in duration.

However, at the time the invention was made, Bureau teaches using electroporation to deliver a transgene to cells of the tissues being treated for regeneration of vasulcarization by angiogenic factors produced by the transgene (column 4). In addition, genes encoding growth factors can be delivered (column 6). The cells are brought into contact with the transgene by topical administration (column 3). "The intensity of the field if between 200 V/cm and 600 V/cm and the total duration is greater than 10 milliseconds" (Column 3). "The number of pulses used is from 1 to 1,000 pulses" (column 3). The electrical pulses can be square wave pulses (column 3). A plasmid can be used to deliver the gene (column 24). However, Bureau does not specifically teach using the method to treat a wound in a patient.

In addition, at the time the invention was made, Ruben teaches that growth factors can be used in therapeutics in the treatment of wounds, burns and other skin disorders (pages 1, 64-69, 88-89 and 134). Ruben further teaches that the administration of a nucleic acid encoding KGF-2 in conjunction with one or more additional nucleic acids that promotes wound healing (page 67). Ruben teaches the electroporation can be used in the gene therapy method (page 69). Ruben teaches using KGF-2 polynucleotide to stimulate wound healing in the normal rat and diabetic mice (page 134).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to wherein the pulse is from 1 microsecond to 5 seconds in duration. One of ordinary skill in the art would have been motivated to combine the teaching because the duration of the pulse was well known to one of ordinary skill in the art as exemplified by Bureau (column 3). See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to treat a cutaneous wound. One of ordinary skill in the art would have been motivated to combine the teaching to promote wound healing.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to treat a burn. One of ordinary skill in the art would have been motivated to combine the teaching to promote wound healing.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to treat a wound in a diabetic patient. One of ordinary skill in the art would have been motivated to combine the teaching to promote wound healing in the diabetic patient.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to surgically removed the wound eschar before administering to a wound site in a patient a plasmid comprising a nucleic acid encoding growth factor operably linked to a promoter to the skin via electroporation. One of ordinary skill in the art would have been motivated to practice the claimed method because to avoid delivering the nucleic acid to the dead skin tissue.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to treat a decubitus ulcer. One of ordinary skill in the art would have been motivated to combine the teaching to promote wound healing in a patient with bed sores.

In addition, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to use one or more nucleic acids encoding at least two growth factors. One of ordinary skill in the art would have been motivated to combine the teaching to enhance the promotion of wound healing.

Furthermore, it would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Zhang taken with Glasspool-Malone in further view of Bureau and Ruben, namely to apply between 1 to 20 pulses of between 500 and 2000 V/cm and between 10 and 1000 microseconds to the wound site. One of ordinary skill in the art would have been motivated to combine the teaching because Bureau teaches that

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those limitations read on standard conditions for one of ordinary skill in the art uses when delivering a nucleic acid in vivo using electroporation. See *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

Claims 1 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Zhang taken with Glasspool-Malone as applied to claims 1, 2, 3, 5, 6, 7, 19, 21, 41, and 44 above, and further in view of Arbeit (US 6,838,430).

Zhang taken with Glasspool-Malone do not specifically teach using a nucleic acid encoding HIF-1 alpha.

However, at the time the invention was made, Arbeit teaches using a nucleic acid encoding HIF-1alpha to accelerate wound healing in a patient (columns 2-3 and 8).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Bureau and Ruben in further view of Arbeit, namely to use a nucleic acid encoding HIF-1alpha in the method. One of ordinary skill in the art would have been motivated to combine the teaching to accelerate wound healing in a patient with a wound.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

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Claims 1 and 42-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over of Zhang taken with Glasspool-Malone as applied to claims 1, 2, 3, 5, 6, 7, 19, 21, 41, and 44 above, and further in view of Braddock et al. (US 6689758).

Zhang taken with Glasspool-Malone do not specifically teach using pin electrodes to apply an electric field to the wound's edges.

However, at the time the invention was made, Braddock teaches:

The healing of skin involves a wide range of cellular, molecular, physiological and biochemical events. During the healing process, cells migrate to wound sites where they proliferate and synthesise extracellular matrix components in order to reconstitute a tissue closely similar to the uninjured original. This activity is regulated by mediators secreted from the wound border cells such as platelet-derived growth factor (PDGF), epidermal growth factor (EGF), transforming growth factor (TGF) beta and other cytokines (column 1).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to combine the teaching of Bureau and Ruben in further view of Braddock, namely to apply the electric field to the wound's edges. One of ordinary skill in the art would have been motivated to combine the teaching improve the transfection of the transgene and increase the activity of mediators secreted from the wound border cells.

Therefore the invention as a whole would have been *prima facie* obvious to one ordinary skill in the art at the time the invention was made.

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***Response to Arguments***

Applicant's arguments, see pages 9-10, filed 11/9/06, with respect to 112 first paragraph have been fully considered and are persuasive. The rejection of claims 1-7, 14, 15, and 17-24 has been withdrawn because of the amendment to claims 1 and 22.

Applicant's arguments, see pages 10-12, filed 11/9/06, with respect to the 103 rejection over Bureau et al. taken with Ruben et al. have been fully considered and are persuasive. The rejection of claims 1-7, 14, 15, and 17-24 has been withdrawn because of the amendment (electric field intradermally) in claim 1 and (applying between 1 and 20 pulses of between 500 to 2000 V/cm and between 10 to 1000 microseconds intradermally) 22.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglas Schultz, PhD, SPE – Art Unit 1635, can be reached at (571) 272-0763.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman

